

**Patent Application No. 09/810,815**  
**Docket No. 00/067NUT**

A<sup>2</sup> 3. (amended) A compound as claimed in claim 1 or 2, wherein the sweetener used is acesulfame or an other oxathiazinone sweetener, alitame, aspartame or a dipeptid or tripeptid based on aspartame, cyclamate or an other sulfamate sweetener, glycyrrhizin, neotame, saccharin or gluconic acid or their physiologically acceptable salts.

Please cancel claims 5 through 9.

## REMARKS

### Introduction

### Status of claims

Claims 1 through 10 are pending; of these, claims 5 through 9 have been withdrawn from consideration as being directed to non elected subject matter. The provisional election of claims 1-4 and 10, made during a telephone conversation with the Examiner is herewith affirmed.

Applicant, however, reserves the right to file one or more divisional applications on the subject matter or request a rejoinder of claims 5 through 9 at a later stage.

Moreover, Applicant wishes to emphasize that the Examiner's reasoning why groups I and II in the restriction requirement are distinct, is clearly erroneous. Applicant's compounds are 'chemical compounds' and no mixtures. To make the compounds according to the present invention, a chemical reaction between at least two starting compounds needs to occur. This cannot be achieved by simply dry mixing the starting compounds.

### The Office Action

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Claims 1 through 4 and 10 have been examined on the merits.

***Rejection under 35 U.S.C. § 112***

Claims 1 through 4 and 10 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in general was not understood grammatically. Applicant agrees with the Examiner in that claim 1 grammatically was incorrect and that its content was not readily apparent.

Applicant has amended claim 1 such that it now unambiguously defines the chemical compounds according to the invention.

Claim 3 has been rejected under 35 U.S.C. § 112, second paragraph, for being indefinite for the use of the term "aspartame-like". The word "-like" renders the claim unclear.

Claim 3 has been reworded to define the "aspartame-like" dipeptids or tripeptids as "dipeptids or tripeptids based on aspartame". Thus, it is clear that dipeptids and tripeptids are meant which are (chemically) derived from aspartame.

It is deemed that by these amendments, the rejections under 35 U.S.C. § 112, second paragraph, are now both moot.

***Rejection under 35 U.S.C. § 102***

Claims 1, 3-4 and 10 have been rejected under 35 U.S.C. § 102(b) as being unpatentable over DE 196 39 343. The Action contends that this reference discloses all that is recited in the claims, since

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it discloses compressed formulations containing nicotine and acesulfame K.

This rejection is traversed for the reasons set forth below.

DE 196 39 343 teaches compressed formulations comprising in a mixture 1-O- $\alpha$ -D-Glucopyranosyl-D-sorbit and optionally a high intensity sweetener such as acesulfame K and optionally a pharmaceutically active substance such as nicotine.

These mixtures are clearly distinct from Applicant's compounds which are no mixtures but homogeneous chemical compounds. The compounds according to the present invention are characterized by a defined stoichiometry. Like H<sub>2</sub>O for water the compounds according to the present invention may e.g. be written as Nic(sw) or Nic(sw)<sub>2</sub> [with Nic = nicotine and sw= sweetener]; see also claim 2. For example, the presently claimed compounds have a unique melting point, whereas mixtures like in DE 196 39 343 would exhibit more than one distinct melting point, each being characteristic for an individual component of the mixture. Likewise, the <sup>1</sup>H-NMR diagrams of the compounds of the present invention show them as homogeneous, distinct chemical compounds and not as mixtures (which would have been detectable). This list of distinctions between mixtures and (chemical) compounds can easily be extended but it is assumed that the Examiner will recognize that the mixtures of DE 196 39 343 do not anticipate the unique chemical compounds according to the present invention.

***Rejection under 35 U.S.C. § 103***

Claim 2 has been rejected under 35 U.S.C. § 103(a) as being obvious over DE 196 39 343 in view of Applicant's admitted art and WO 00/12067.

DE 196 39 343 as stated above teaches mixtures and no chemical compounds of sweeteners/nicotine. There is nothing in DE 196 39 343 which would lead one skilled in the art to

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chemically join a sweetener and nicotine to yield a chemically homogeneous compound. This inevitably would require a chemical reaction between a sweetener and nicotine in some way (as it is disclosed in the present specification). There is nothing in DE 196 39 343 which would suggest this. Moreover, DE 196 39 343 is not even a suggestion to combine a sweetener and nicotine. Sweeteners and pharmaceutically active substances are only mentioned as optional additives to 1-O- $\alpha$ -D-Glucopyranosyl-D-sorbit. Anion forming sweeteners such as acesulfame and nicotine as pharmaceutically active agents are only mentioned as members of extensive lists of optional additives. Nothing in DE 196 39 343 would motivate one skilled in the art to specifically select e.g. nicotine from the numerous pharmaceutically active agents. But even if one skilled in the art would have selected an anion forming sweetener and nicotine from DE 196 39 343 he would not have resulted in Applicant's new compounds. At best he would have resulted in a mixture of 1-O- $\alpha$ -D-Glucopyranosyl-D-sorbit, a sweetener and nicotine.

This deficiency in DE 196 39 343 cannot be cured by Applicant's admitted art or WO 00/12067. Applicant's admitted art - which includes WO 00/12067 - does neither teach nor suggest compounds made of a sweetener and nicotine. Those compounds are not obvious in the light of e.g. WO 00/12067. It is not predictable whether a given bitter tasting compound will react with a given sweetener to yield a salt or a homogeneous chemical compound. The properties - and here specifically the taste - of a chemical compound in general are unpredictable. It is known that e.g. acesulfame is a high intensity sweetener. This is due to its unique chemical structure. The replacement of a single atom in this structure or the attachment of even a small chemical group may completely alter the taste of this slightly modified molecule. It was completely unpredictable whether a 'chemically combined' nicotine/sweetener molecule would possess the nicotine's bitter taste or the sweeteners sweet taste or something completely different. Therefore, WO 00/12067 does not obviate Applicant's new compounds, neither alone nor in any combination. Even less is there a motivation to be found in any of the cited prior art to make compounds with a stoichiometry of 1:2 as claimed in claim 2.

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In the light of the above amendments and remarks favorable reconsideration is respectfully requested.

Should Examiner Dionne A. Walls have any questions regarding the present application, the Examiner is invited to contact the undersigned.

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**Appendix Indicating Changes to Claims**

1. (amended) A compound of nicotine and a sweetener or of nicotine and sweeteners as well as ~~acid-addition salt with their physiologically acceptable salts a physiologically acceptable acid or acid addition salts with a physiologically acceptable acid.~~

3. (amended) A compound as claimed in claim 1 or 2, wherein the sweetener used is acesulfame or an other oxathiazinone sweetener, alitame, aspartame or ~~an aspartame-like a dipeptid or tripeptid based on aspartame,~~ cyclamate or an other sulfamate sweetener, glycyrrhizin, neotame, saccharin or gluconic acid or their physiologically acceptable salts.